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Large Laser Sheaths for Pacing and Defibrillator Lead Removal

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Background and Objective: **In a recent clinical trial, the 12-F laser sheath showed 95% success in completely explanting chronically implanted pacing leads smaller than 7.5-F diameter. For larger leads, two new sizes of laser sheath have been implemented, the 14-F and 16-F (outer diameter) devices, which accommodate leads up to 9.5- and 11.5-F, respectively. The object of this study was to determine the cutting ability of the larger devices compared to the 12-F design.**
Materials and Methods: **The rate of device advancement through fresh porcine aorta was measured for three sizes of laser sheath as pulsed ultraviolet light from a 308-nm XeCl excimer laser was applied. Dependent variables were fluence (mJ/mm^2), laser pulse repetition rate, and pressure applied between the device and the tissue.**
Results: **At 60 mJ/mm^2, 40 Hz repetition rate and 1.4 kg/cm^2 pressure, all devices produced cutting rates in the range of 9–13 μm/pulse. Improvement in advancement per laser shot can be attained by increasing any independent variable studied.**
Conclusions: **Physicians must apply only slightly greater force to the larger laser sheaths, and maximum available repetition rate and fluence implies maximum cutting speed. Lasers Surg. Med. 22:42–45, 1998.**

Key words: 308-nm excimer laser; pacing leads; fiber optics

INTRODUCTION

In a recently completed randomized clinical trial, the 12-F laser sheath was shown to be more effective than standard tools alone in explanting chronically implanted pacing leads [1]. Standard tools were defined as telescoping polymer or stainless steel sheaths, locking stylets, grips, snares, suture, etc., which were in common use [2] prior to 1996. In a typical case with standard tools, after a locking stylet has been placed in the lead, two telescoping sheaths are threaded over the lead toward the heart. Along the way, the sheaths dilate or tear scar tissue that adheres the lead to the vein and heart wall.

The laser sheath [3] replaces the inner sheath of a polymer sheath set. Optical fibers imbedded in the device conduct laser light to the distal tip of the sheath (see Fig. 1). When ultraviolet light pulses from a Spectranetics (Colorado Springs, CO) CVX-300 Excimer Laser are administered, the resulting tissue ablation at the tip of the laser sheath allows it to cut through adherent scar [4]. Using the laser, investigators achieved a 50% increase in success rates over standard tools.

In the randomized trial, one size of laser sheath was available to target leads with outer diameter less than or equal to 7.5 F (3 F = 1 mm). For larger bradycardia and defibrillator leads, larger devices are required. Two larger laser sheath designs are designated to meet this need. This study was undertaken to compare the functional characteristics of the larger laser sheaths to the 12-F laser sheath and to determine if a significant difference in clinical performance can be expected.

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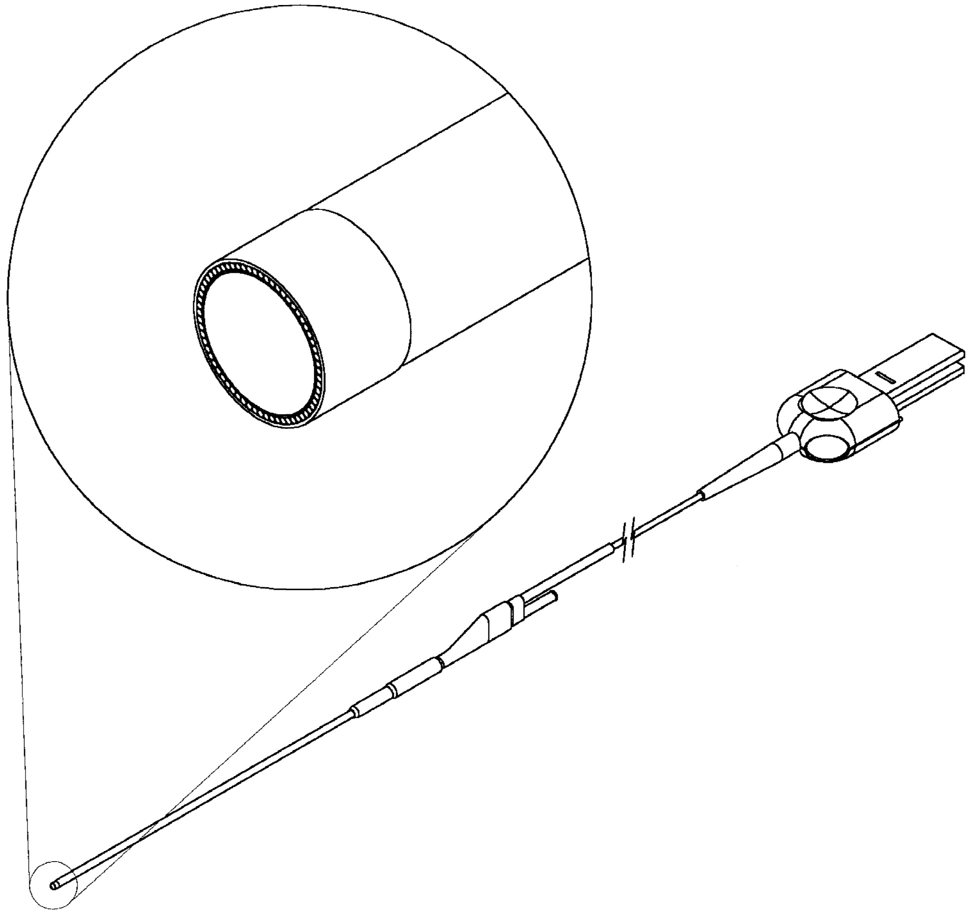

Fig. 1. The working section of the laser sheath comprises a tubular member through which a pacing lead is threaded. At the tip of the device, a ring of optical fibers emits pulsed laser light to ablate tissue. The fibers bifurcate away from the working section and are terminated at the proximal end in a laser connector.

MATERIALS AND METHODS

Typical design features of the laser sheath can be seen in Figure 1. The working section provides a tubular portion with unobstructed inner lumen through which the pacing lead is threaded. The polished ends of the optical fibers are presented at the very tip of the working section. At the proximal end of the working section, the fibers bifurcate away from the working section into a tail tubing. A bifurcate cover protects the fibers and provides a convenient gripping point. A laser connector terminates the fibers at the proximal end of the tail tubing.

The working section comprises an inner and an outer extruded polymer tubing. For the 12-F laser sheath, the inner tubing is polyester elastomer, whereas polyethylene is used in the 14-F and 16-F devices. The outer tubing is polyethylene. At the distal end of the catheter, the fibers are potted in epoxy between inner and outer, beveled, stainless steel bands. Between the distal end and the bifurcate, the fibers are spirally wrapped between the inner and outer tubings. This feature lends flexibility to the working section.

Table 1 provides a comparison of the dimensions of the laser sheaths.

To study the rate at which the laser sheath advances through tissue, the device under study was attached to one end of a 35-cm-long first-class lever with a ball-bearing fulcrum. An adjustable counterweight occupied the other end of the lever. The device tip rested on a tissue sample, which in turn rested on a Sartorious B4100 electronic scale. The counterweight was adjusted to achieve the desired force between the device tip and the tissue.

Prior to attaching the device to the lever, the device was connected to a CVX-300 XeCl excimer laser, which delivers up to 160 mJ of light at 308 nm. The output of the laser sheath was read by a

TABLE 1. Physical Dimensions of Laser Sheaths

	12-F laser sheath	14-F laser sheath	16-F laser sheath
Min ID	8.2 F	10.2 F	12.5 F
Max OD	12.5 F	14.9 F	17.5 F
Working length	40 cm	40 cm	40 cm

Molectron model JD500 joulemeter, and the laser was adjusted to obtain the desired output energy from the device tip. Typically this fell in the range of 40–50 mJ. Fluence was defined as device output energy divided by the total cross-sectional area of all fibers in the device. For reference, the settings currently used clinically are 60 mJ/mm^2 and 40 Hz.

With the apparatus ready, the laser was activated until the laser sheath completely penetrated the tissue sample. Advancement rate was then calculated by dividing the premeasured (Mitutoyo snap gauge model 7305) tissue thickness by the number of laser pulses required for penetration. These studies used one piece of porcine aorta, frozen in 0.9% saline within 4 hours of harvest and thawed in 21°C 0.9% saline before use. The samples are typically 1.5 mm thick.

Three laser sheaths were studied at various laser and lever settings. For each setting, three measurements of advancement were made and averaged for the results presented below.

RESULTS

The three devices advanced easily through porcine aorta; penetration typically occurred in approximately 200 pulses. Figure 2 shows that the rate of advancement follows a rather linear increase with laser repetition rate, when the advancement is expressed in microns per second.

Figure 3 plots the effect of fluence on the process for a clinically relevant range of device outputs. Increasing the applied force of the device tip onto the tissue had a profound effect on penetration rate, as shown in Figure 4. Error bars in the plots are the size of ±1 standard deviation.

DISCUSSION

The effect of fluence on cutting ability (Fig. 3) shows features similar to excimer laser coronary angioplasty (ELCA) [5–7]. The plots depict a threshold fluence, below which advancement will not occur. In this case, the threshold is approximately 30 mJ/mm^2, in close agreement with research on angioplasty [7–9]. Advancement increases with fluence, up to the highest fluence tested (80 mJ/mm^2).

Previous detailed work on the laser-tissue interaction for ELCA has shown that the ablation mechanism combines photochemical decomposition of cellular structures with explosive photothermal vaporization of cellular water [9,10]. The latter effect produces a transient steam bubble at the tip of the device, with a lifetime of approximately 100 μs and a size 1–3 times the diameter of the fiber. Damage to collateral tissue, such as parting tissue lamellae, is ascribed to the transient bubble in cases in which the bubble is confined beneath the tip of the device [9]. When the

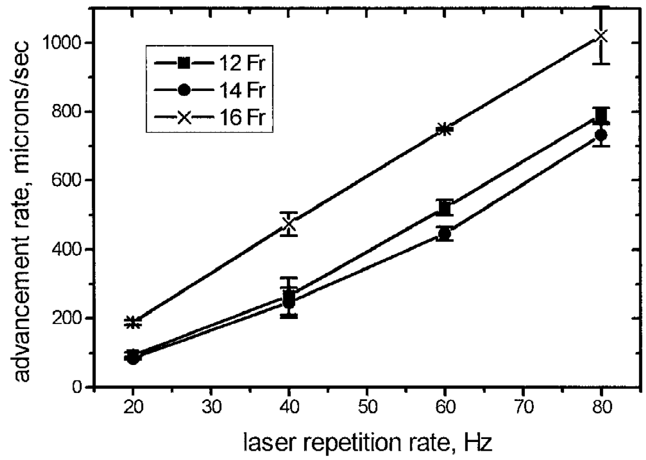

Fig. 2. The laser sheath advances through soft tissue with a speed that is approximately linearly related to the laser repetition rate. Conditions were 60 mJ/mm^2 and applied pressure 1.4 kg/cm^2.

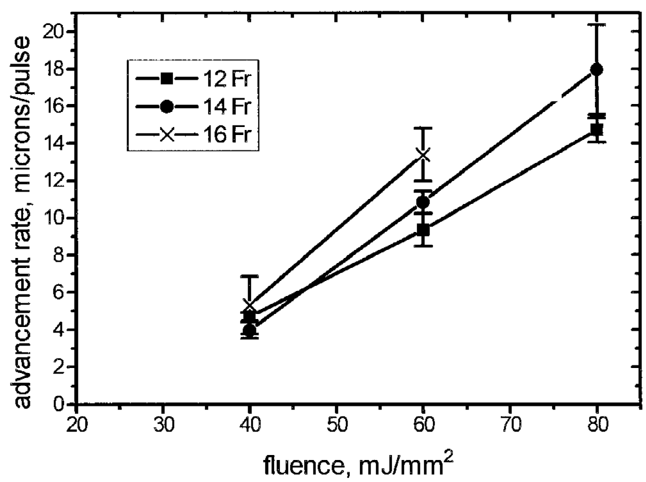

Fig. 3. Higher fluence increases the ability to advance through soft tissue. Conditions were 40 Hz repetition rate and applied pressure 1.4 kg/cm^2.

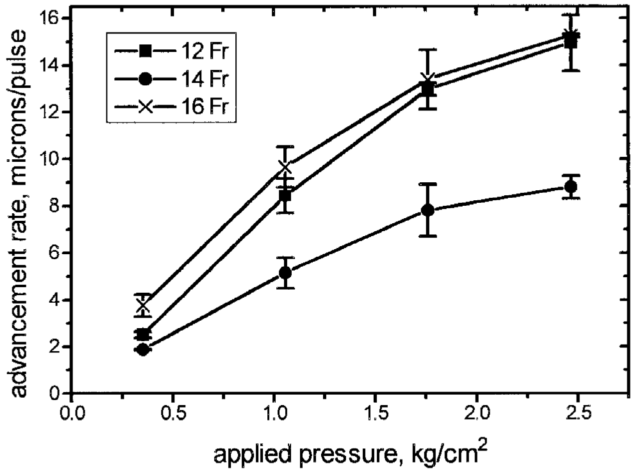

Fig. 4. The ability to advance through soft tissue increases with the force applied at the device tip. Conditions were 40 Hz repetition rate and fluence 60 mJ/mm^2.

applied force is 10 g or less, ELCA ablation at the rate of approximately 2 μm per shot is achieved [7].

Figure 4 shows advancement rates far in excess of the value typically reported for the ability of this wavelength of light to ablate on each shot. This suggests that the laser sheath takes advantage of the mechanical damage inflicted on the tissue under the device tip to start a microscopic tear. The data show that the combined effect of tissue ablation plus tissue tearing will reach 15 μm per shot at the highest forces tested. Evidence of a plateau just above 2.5 kg/cm^2 suggests that this tear cannot be propagated much more than this value, however. The clinical implication is that the tip must experience 1.5–2.5 kg/cm^2 of force to advance through tissue, but higher forces than this offer only marginal advantage.

One difference between the results discussed here and the expected clinical situation lies in the tissue type encountered. These tests in porcine aorta ablated tissue with high elastin content, whereas high collagen content should be expected in an intravascular scar. Previous work [11] showed that ablation rates in collagen-rich tissue were approximately 25% below that of aortic wall. Therefore these test results should be viewed as an upper bound for advancement rates in the expected clinical application.

In conclusion, three sizes of laser sheath advance at reasonable rates through soft tissue at current clinical parameter settings. The devices behave similarly, under comparable conditions, with some variation between the sizes. Advancement rates depend on fluence, laser repetition rate, and the force applied between the device tip and the tissue. Increased performance may be achieved at higher fluence and/or laser repetition rate.

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